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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,818	12/05/2005	Lidia Ivanova	26602U	1648

20529 7590 12/21/2007  
NATH & ASSOCIATES  
112 South West Street  
Alexandria, VA 22314

EXAMINER
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CHEN, SHIN LIN

ART UNIT	PAPER NUMBER
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1632

MAIL DATE	DELIVERY MODE
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12/21/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/524,818

**Applicant(s)**

IVANOVA ET AL.

**Examiner**

Shin-Lin Chen

**Art Unit**

1632

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-85 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-85 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-56 and 63-77, drawn to a nucleic acid molecule comprising (A) a first polynucleotide encoding an RNA molecule, said RNA comprising at least one cis-acting sequence, a first nucleotide sequence encoding an RNA-dependent RNA polymerase and at least one second nucleotide sequence selected from (i) a second open reading frame encoding a polypeptide, (ii) a nucleotide sequence complementary to all or part of the second open reading frame of (i), and (iii) a nucleotide sequence encoding an untranslated RNA molecule or complement thereof, (B) a second polynucleotide comprising an origin of replication, and (C) a third polynucleotide encoding a replication initiation factor recognizing said origin of replication, An expression system comprising said nucleic acid molecule, a method of producing a host cell comprising said nucleic acid molecule, and the host cell produced by said method.

Group II, claim(s) 57-62, drawn to a method of making a recombinant host cell comprising introducing the nucleic acid molecule of claim 1 into a host cell.

Group III, claim(s) 78-81, drawn to a method for producing a polypeptide or untranslated RNA molecule by introducing the nucleic acid molecule of claim 1 into a host cell.

Group IV, claim(s) 82-85, drawn to a method for regulating the expression of a polypeptide or an untranslated RNA molecule by introducing the nucleic acid molecule of claim 18 into a host cell.

2. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The putative special technical feature shared by groups I-IV is the nucleic acid molecule comprising the recited elements (A) to (C) in claim 1. Renner et al., 1999 (WO 99/50432, IDS AM2) discloses a DNA molecule comprising a polynucleotide encoding an RNA molecule, said RNA molecule comprising (a) at least one cis-acting sequence element, (b) a first open reading frame having a nucleotide sequence encoding a non-sytopathic, temperature-sensitive RNA-dependent RNA polymerase, and (c) at least one second nucleotide sequence having (i) a second open reading frame encoding a protein, (ii) a sequence complementary to all or part of the second open reading frame or (i), or (iii) a sequence encoding an untranslated RNA molecule or complement thereof, A method of making a recombinant host cell by using said DNA molecule, an in vitro cell culture comprising a recombinant host cell produced by said method, and an RNA molecule transcribed from said

DNA molecule (e.g. p. 58-59). The DNA molecule comprise a 5' promoter capable of initiating synthesis of RNA in vivo, 5' and/or 3' sequence enabling replication of the RNA molecule (origin of replication) (e.g. p. 18, 1<sup>st</sup> full paragraph). The sequence encoding the RNA-dependent RNA polymerase also can be considered the third polynucleotide element encoding a replication initiation factor because the RNA-dependent polymerase can initiate RNA replication from the 5' origin of replication. Further, the nonstructural genes 1-4 in the vector presented in Figure 2 can encode more than one replicase, i.e. RNA-dependent RNA polymerase. It also would be obvious for one of ordinary skill in the art at the time of the invention to put one more polynucleotide sequence encoding a replication initiation factor in the RNA molecule in order to initiate the replication of RNA. Thus, no special technical feature has been contributed by the instant invention over the prior art. Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Origin of replication:

- (1) prokaryotic
- (2) eukaryotic
- (3) viral origin

Replication initiation factor:

- (1) prokaryotic
- (2) eukaryotic
- (3) viral origin

RNA-dependent RNA polymerase:

- (1) temperature-sensitive RNA-dependent RNA polymerase
- (2) noncytopathic RNA-dependent RNA polymerase
- (3) temperature-sensitive, non-cytopathic RNA-dependent RNA polymerase

And further specie election from:

- (1) Bebaru virus
- (2) Cabassou virus
- (3) Chikingunya virus
- (3) Easter equine encephalomyelitis virus
- (4) Fort morgan virus
- (5) Getah virus
- (6) Kyzylagach virus
- (7) Mayoaro virus
- (8) Middleburg virus
- (9) Mucambe virus
- (10) Ndumu virus
- (11) Pixuna virus
- (12) Tonate virus
- (13) Trinita virus
- (14) Una virus
- (15) Western equine encephalomyelitis virus
- (16) Whataroa virus
- (17) Venezuelan equine encephalomyelitis virus (VEE)

- (18) Ross River virus
- (19) alpha virus
- (20) Sindbis virus
- (21) Semliki Forest virus
- (22) Aura virus.

Second open reading frame encoding:

- (1) cytokine
- (2) lymphokine
- (3) tumor necrosis factor
- (4) interferon
- (5) toxic polypeptide
- (6) prodrug or converting enzyme
- (7) antisense RNA molecule
- (8) tRNA molecule
- (9) rRNA molecule
- (10) ribozyme

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner:

The claims corresponding to the elected species

The following claim(s) are generic: 1, 2, 8, 9, 13-18, 26, 27, 33, 34, 38-48, 57-75 and 77-85.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: They represent different origin or replications, replication initiation factors, RNA-dependent RNA polymerase and polypeptides. They do not share common core structures and they have different biological functions.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In

either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also



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enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shin-Lin Chen, Ph.D.

A handwritten signature in black ink, appearing to read 'S-L Chen', located to the right of the printed name.